

Good Laboratory Practices

CLIA Non-Waived Tests – Moderately Complex

Required

- ❑ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments – 1988) Certificate of Compliance or Certificate of Accreditation

Application www.cms.hhs.gov/clia

- ❑ Perform any test categorized by FDA (Federal Drug Administration) as waived + moderate complexity tests listed on your CLIA certificate

List www.accessdata.fda.gov/scripts/cdrh/cfdoc/cfCLIA/search.cfm

- ❑ Follow manufacturer's instructions and agency's requirements

For compliance regulations www.cms.hhs.gov/clia

CLIA Regulations & Federal Register Documents (left column)

For accredited standards – follow agency requirements

Personnel qualifications www.cms.hhs.gov/clia CLIA Regulations & Federal Register Documents (left column)

- ❑ Director – 493.1405 & 493.1406 (duties 493.1407)
- ❑ Clinical Consultant – 493.1417 (duties 493.1419)
- ❑ Technical Consultant – 493.1411 (duties 493.1413)
- ❑ Testing Personnel – 493.1423 (duties 493.1425)

Oversight

- ❑ Cost – varies by agency and test volume every 2 years
- ❑ Surveys – every two years

State agencies schedule visits within 2 weeks

Accrediting agencies scheduled versus unannounced = varies